

### **Remarks**

Claims 59-65, 67, 68, 71-78, 80-86, 88-90, 92-109 and 110-111 are pending in this application. Claims 67, 68, 71-78, 80-86, 88-90 and 92-102 are withdrawn from consideration by the Examiner. Claims 59-65, 67, 78, 86, 89, 90, 104-106 and 108 are amended herein. Claims 103 and 107 are canceled herein. Claims 110-111 are newly added.

Claim 59 is amended to incorporate the limitations of claim 107. Additional support for the amendments to the claims can be found throughout the specification, such as on pages 1-5, the Examples section, the figures and the original claims. Claim 104 is amended to correct dependency.

New claims 110-111 are added. Claim 110 is added to refer to the SHED cells, as deposited with the ATCC. Support for new claim 111 can be found in the specification, such as on pages 27-28.

The specification is amended herein to reference a deposit made in accordance with the Budapest Treaty.

Reconsideration of the present application is respectfully requested in view of the foregoing amendments and following remarks.

### **Rejection Under 35 U.S.C. § 112, First Paragraph**

Claims 59-65, 103-107 and 109 are newly rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement and encompassing new matter. Applicants respectfully disagree with this rejection.

The Office action acknowledges that the specification provides support for cells that can proliferate for over 140 population doublings, and that these cells are "SHED" cells. However, the Office action asserts that SHED cells are not purified cells, but rather a mixed population of cells that are termed "SHED" so that the proliferative capacity of any individual cell is unknown. The Office action asserts that the specification does not describe that cells with the markers specified in the claims that can proliferate for 140 doublings. Applicants respectfully disagree.

Clonal cell populations of SHED cells are described in the specification (see page 27, line 29). All of these clonal populations of cells induce bone formation upon transplantation. These cells also differentiate into cells expressing neurofilament and can form adipose tissue (see Figs. 9, 10, pages 16-17 and pages 27-28).

The U.S. PTO has previously cited Gronthos et al., (*J. of Dental Research* 81(8): 531-535,

2002). As noted by the U.S. PTO (see the Office action dated January 4, 2010), Gronthos et al. discloses dental pulp stem cells (DPSCs) obtained from amputated human third molars of adults (19-29 years old; see page 531) and compares these cells to human bone marrow stromal stem cells (BMSSCs, also known as BMSCs). The U.S. PTO has also cited Gronthos et al., (*PNAS* 97(25): 13625-13630, 2000), which discloses dental pulp stem cells (DPSCs) obtained from amputated human third molars of adults (19-29 years old; see page 13625) and compares these cells to human bone marrow stromal cells (BMSCs). In addition, the U.S. PTO has cited Shi et al., (PCT Publication No. WO 02/07679, January 2002). Shi et al. disclose dental pulp stem cells (DPSCs) obtained from amputated human third molars of adults of at least 18 years of age (see page 6), such as subjects 19-29 years of age (see page 9). Shi et al. compares these cells to human bone marrow stromal stem cells (BMSCs, see page 13). However, DPSCs are very different than the presently claimed cells.

The specification provides evidence that human postnatal deciduous dental pulp multipotent stem cells from exfoliated teeth (*i.e.*, stem cells from a human exfoliated deciduous tooth or “SHED”; see page 10, lines 17-20 of the specification) are not the same as DPSCs, such as those disclosed by Shi et al. For example, the specification teaches that the proliferation rate of the claimed cells is different than DPSCs, such as those described in Shi et al. (see Figures 5G and 5H of the specification, which are discussed in more detail above). As disclosed in the specification, the claimed cells (SHED) can proliferate to over 140 population doublings, while DPSCs only proliferate for up to 100 population doublings. Thus, SHED have at least a 150% higher proliferative capacity when compared to DPSCs.

Submitted herewith is a copy of Miura et al., *Proc. Natl. Acad. Sci.* 100: 5807-5812, 2003, which provides a description of both the presently claimed cells (SHED) and DPSC. Miura et al. disclose that SHED can induce the formation of bone (have osteoinductive capacity); DPSCs do not have this ability. Miura et al. conclude that SHED and DPSC are entirely different cells, as they have different proliferation rates, cell-population doublings, sphere-like cell cluster formation, and form different cells when transplanted in vivo. Thus, the previously cited prior art cannot be construed to anticipate, or render obvious, the presently claimed cells.

### **Biological Deposit**

In order to advance prosecution, claim 110 has been added that refers to specific populations of cells that have the characteristics of the human postnatal deciduous dental pulp multipotent stem

cell (SHED) as deposited in accordance with the Budapest Treaty with the American Type Culture Collection (ATCC) as ATCC Deposit Number PTA-11551 on December 15, 2010. As set forth in MPEP, an original deposit thereof may be made at any time during pendency of the application for patent. As noted in the Deposit receipt, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent, with the exceptions provided for in 37 C.F.R. 1.808(b). A statement is submitted herewith from Dr. Akiyama, who is in a position to corroborate the fact, stating that the biological material which was deposited was a biological material specifically identified in the application as filed.

### **Claim Objection**

Claim 103 is objected for allegedly being objected to as being of improper dependent form for failing to further limit the subject matter of the previous claim. Claim 103 is canceled herein, rendering the rejection moot.

### **Conclusion**

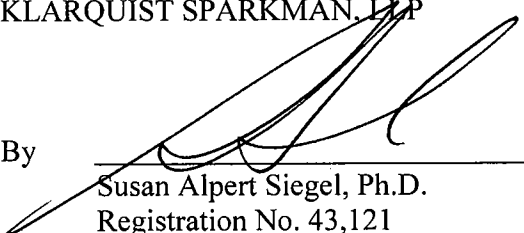
Following entry of this amendment, Applicants believe that the present claims are in condition for allowance, which action is requested. *If any issues remain prior to allowance, the Examiner is formally requested to contact the undersigned prior to issuance of an Advisory Action, in order to arrange a telephonic interview.* It is believed that a brief discussion of the merits of the present application would expedite prosecution and allowance. This renewed request is being submitted under MPEP §713.01, which indicates that an interview may be arranged in advance by a written request.

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